K130256

7. 510(K) SUMMARY

JUL 0 2 2013

Introduction:

This document contains the 510(k) Summary for the MDK Multi-Applications Platform. The content of this summary is based on the requirements of 21 CFR 807.92(c).

Applicant / Manufacturer Name and Address:	Quanta System SPA Via IV Novembre, 116 Solbiate Olona (VA) Italy, 21058
510(k) Contact Person:	Maurizio Bianchi Regulatory Affairs Manager Quanta System SPA Email: maurizio.bianchi@quantasystem.com Phone: +39 0331 376797 Fax: +39 0331 367815
Date Prepared:	November 20th, 2012
Device Name:	MDK Multi-Applications Platform
Classification:	Class II
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
.Regulation Number:	21 CFR 878.4810
Product Code:	GEX

Predicate Devices:

The MDK Multi-Applications Platformis claimed to be substantially equivalent to the following legally marketed predicate devices:

- Ultrawave II (K070805) – Quanta System SpA
- Ultrawave III (K083207) – Quanta System SpA
- Q-Plus T (K073549) – Quanta System SpA
- Q-Plus T +IPL (K123168) – Quanta System Spa

Performance Standards:

There are no mandatory performance standards for this device.

General Device Description:

The MDK Multi-Applications Platform is laser surgical instrument for use in general and plastic surgery and in dermatology (GEX). The device includes a Q-Switched Nd:YAG laser source emitting at 1064 nm and 532 nm wavelengths, and/or an Nd:YAG laser source emitting at 1064 nm (short and long pulse) and/or at 1320 nm and/or at 532 nm, and/or an Alexandrite laser source emitting at 755 nm (long pulse) and/or an intense pulsed light (Twain IPL Handpiece).

The optical delivery system for the Q-Switched Nd:YAG laser source (1064nm and 532nm) is an articulated arm with fixed handpieces. The optical delivery system for the Nd:YAG laser source (1064nm long/short pulse, 755 nm long pulse, 532 nm long pulse and 1320 nm long pulse) is an optical fiber with focusing handpieces up to 12mm spot size. The optical delivery system for the IPL system is an handpiece (Twain IPL) with interchangeable light filter at different wavelengths.

IMPORTANT NOTE: The MDK Multi-Applications Platform control software allows to work only one laser source or IPL at time: it means that the laser sources works separately and indipendently. Moreover the Intense Pulse Light cannot work with any laser sources. Combined (simultaneously or sequentially) operations of different laser sources and/or IPL is not allowed.

The MDK Multi-Applications Platform architecture is based on the following main sub-systems: (1) an high voltage power supply, which converts and rectifies the AC mains current to provide regulated power for the flash-lamps, simmer current and main triggering pulse; (2) a cooling system consisting of an internal water flow circuit together with water-to-air heat exchanger; (3) a Q-switched Nd:YAG laser source, capable of generating very short pulses at 1064nm and at 532 nm through a suitable (4) KTP SGH crystal, capable of converting light pulses at 1064nm into light pulses at 532nm; (5) a Nd:YAG laser source, capable of generating laser pulses at 1064nm or 1320nm wavelength and at 532 nm through a suitable (6) KTP SGH crystal, capable of converting light pulses at 1064nm into light pulses at 532nm; (7) an Alexandrite laser source, capable of generating laser pulses at 755nm with frequency up to 1,5 Hz; (8) an Intense Pulsed Light handpiece system (Twain IPL), capable of generating light pulses at a frequency of 0.5 Hz; (9) the microprocessor based controller, which regulates the functions of the laser and allows parameter selection by the user; (10) an optical delivery system, interfacing the energy from the laser to the patient via an articulated arm and focusing hand piece; (11) an optical delivery system, interfacing the energy from the laser to the patient via an optical fiber and focusing hand piece; and (12) an integral skin cooler.

The MDK Multi-Applications Platform is controlled via a touch screen display hosted in the front of the device where are also located the key switch, the emergency red push button and the operation led. On the rear panel the footswitch connector, the remote interlock and the power switch are located.

Indications for Use

The MDK Multi-Applications Platform is laser surgical instrument for use in general and plastic surgery and in dermatology (GEX).
The MDK Multi-Applications Platform is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization and coagulation in the medical specialties of dermatology, general and plastic surgery, endoscopic/laparoscopic general surgery, gastroenterology, gynecology, neurosurgery, otorhinolaryngology (ENT), oculoplastic, oral surgery, ophthalmology (skin around eyes), orthopedics, podiatry, pulmonary/thoracic surgery and urology for surgical and aestetic applications.

For intended use in Dermatology for the coagulation and hemostasis of benign vascular leasion such as, but not limited to, rosacea, poikiloderma of civatte, and treatment of benign cutaneous lesions such as warts, scars and straie. Also intended for treatment of wrinkles as, but not limited to, periocular and perioral wrinckles.

For intended use on all skin types (Fitzpateick I-VI), including tanned skin.

Comparison of Technological Characteristics:

The specifications for the MDK Multi-Applications Platform is substantially equivalent to the specifications for its identified predicate devices with respect to the laser and IPL sources, wavelengths, maximum energy, spot size, fluence, pulse width, repetition rate, beam delivery, power monitor, actuator, and aiming beam.

Comparison of Intended Use:

The intended use of the MDK Multi-Applications Platform is the same as the intended use of its previously cleared devices.

Substantial Equivalence:

The Quanta System MDK Multi-Applications Platform is as safe and effective as the predicate devices.
The MDK Multi-Applications Platform has the same intended use and similar technological characteristics and principles of operation as its predicate devices. The

minor technological differences between the MDK Multi-Applications Platform and its predicate devices raise no new issues of substantial equivalence or safety and effectiveness.

Thus, MDK Multi-Applications Platform is substantially equivalent to its identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

July 2, 2013

Quanta System SpA
% Mr. Maurizio Bianchi
Via IV Novembre No 116
21058 Solbiate Olona (VA), Italy

Re: K130256
Trade/Device Name: MDK Multi-Applications Platform
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general surgery and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: June 01, 2013
Received: June 05, 2013

Dear Mr. Bianchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K130256

Device Name: MDK Multi-Applications Platform

Indications for Use:

The MDK Multi-Applications Platform is is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization and coagulation of body soft tissues
In the medical specialties of dermatology, general and plastic surgery, endoscopic/laparoscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oral surgery as follows:

Nd:YAG 1064nm Q-switched and 532nm Q-switched
The MDK Multi-Applications Platform is intended for treatment of vascular lesions, pigmented lesions, and for hair, tattoo removal and the incision, excision, ablation, vaporization of soft tissue.

General dermatology
(ablation, vaporization, incision, excision and coagulation of soft tissue) indicatated for treatment such as, but not limited to treatment of:

Tattoo removal
- 1064nm: suggested for dark blue and black ink
- 532nm: suggested for red, orange, yellow, and purple ink

Pigmented lesion removal (benign)
- Café au lait spot
- Ephelides, solar lentigo (lentigines)
- Becker Nevus
- Ota Nevus
- Nevus spilus

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Surgical Devices

510(k) Number K130256

Indications for Use Statement

510(k) Number (if known): K130256

Device Name: MDK Multi-Applications Platform

Indications for Use: continued

Nd:YAG 1064nm (long & short pulse)
The MDK Multi-Applications Platform is intended for general surgical applications; dermatology/plastic surgery; endoscopic - laproscopic surgery; general surgery; gynecology; ENT; hemostasis; neurosurgery; oculoplastics; pulmonary surgery; thoracic surgery; urology; and orthopedics.

General Surgical Appl.:
Incision, excision, coagulation, hemostasis, vaporization, and/or ablation of soft tissue in dermatology & plastic surgery, endoscopic - laparoscopic general surgery, gastroenterology, general surgery, gynecology, head and neck/-otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary surgery, thoracic surgery and urology.

Dermatology/Plastic Surgery:
Coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg and spider veins and poikiloderma of Civatte and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. It addition, the laser is intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of blue and/or black tattoos), and plaques.
The laser is also indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
The laser is also indicated for the treatment of facial wrinkles.
It is indicated for the removal of unwanted hair, for the stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment of pseudofolliculitis barbae (PFB). Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.
It is indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
It is indicated for use on all skin types (Fitzpatrick I-VI) including tanned skin, and the removal and permanent reduction of unwanted hair in Fitzpatrick I-VI, including suntanned skin types.

Orthopedics:
Cutting, ablation, and/or hemostasis of intra-articular tissue in orthopedic surgical and arthroscopic applications.

Pulmonary Surgery:
Palliative treatment of benign and malignant pulmonary airway obstructions, including squamous cell carcinoma, adenocarcinoma, carcinoid, benign tumors, granulomas, and benign strictures.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

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Division of Surgical Devices

510(k) Number K130256

Indications for Use Statement

510(k) Number (if known): K130256

Device Name: MDK Multi-Applications Platform

Indications for Use: continued

Nd:YAG 1064nm (long & short pulse) - Continued
Thoracic Surgery:
Incision, excision, coagulating and vaporization of soft tissue. Thoracic applications, including but not limited to, isolation of vessels for endarterectomy and/or by-pass
grafts, wedge resections, thoractomy, formation of pacemaker pockets; vaporization, coagulation, incision/excision, debulking, and ablation of lung tissue (thoracoscopy).
Urology:
All applications including superficial urinary bladder tumors, invasive bladder carcinoma, urethral strictures and lesions of the external genitalia (including condyloma acuminate).

Nd:YAG 1320nm
Indicated for use in general surgery and dermatology for the incision, excision, ablation, vaporization, coagulation and haemostasis of soft tissue. It is also indicated for the treatment of periorbital and perioral wrinkles, fine lines and wrinkles, and the treatment of back acne and atrophic acne scars.

Alexandrite 755 nm
Intended for coagulation and hemostasis of vascular lesions and the removal and permanent reduction of unwanted hair in Fitzpatrick skin types I-VI, including suntanned skin types.Also indicated for pigmented lesions and wrinkles. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

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Division of Surgical Devices

510(k) Number K130256

Indications for Use Statement

510(k) Number (if known): K130256

Device Name: MDK Multi-Applications Platform

Indications for Use: continued

Nd:YAG 532nm (Long pulse)
For the coagulation and hemostasis of vascular lesions.

Dermatology/Plastic Surgery:
For photocoagulation and hemostasis of vascular and cutaneous lesions in dermatology including but not limited to, the following general categories: vascular lesions [angiomas, hemangiomas (port wine), telangiectasia (facial or ex-tremities telangiectasias, venous anomalies, leg veins]; benign pigmented lesions (nevi, lentigines, chloasma, cafe au- lait, tattoos (red and green ink), verrucae, skin tags, keratoses, plaques, cutaneous lesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size.

General Surgery:
Vaporizing, Coagulating, Incising, Excising, Debulking, and Ablating of Soft Tissue as well as in Endoscopic (e.g., laparoscopic) or open surgeries.

Gastroenterology:
Tissue ablation and hemostasis in the gastrointestinal tract; Esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma; Gastrointestinal hemostasis (including Varices, Esophagitis, Esophageal Ulcer, Mallory-Weiss tear, Gastric Ulcer, Angiodysplasia, Stomal Ulcers, Non-bleeding Ulcers, Gastric Erosions); Gastrointestinal Tissue ablation (Benign and Malignant neoplasm, Angiodysplasia, Polyps, Ulcer, Colitis, Hemorrhoids).

Head and Otorhinolaryngology (ENT):
Tissue incision, excision, ablation, and vessel hemostasis.

Hemostasis during Surgery:
Adjunctive coagulation and hemostasis (bleeding control) during surgery in endoscopic (e.g., laparoscopic) and open surgery.

Neurosurgery:
Hemostasis for: Pituitary Tumor, Meningioma; hemagioblastoma; AVMs; Glioma; Glioblastoma; Astrocytoma; Oligodendroglioma.

Ophthalmology:
Post-vitrectomy endophotocoagulation of the retina.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

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Division of Surgical Devices

510(k) Number **K130256**

Indications for Use Statement

510(k) Number (if known): K130256

Device Name: MDK Multi-Applications Platform

Indications for Use: continued

Nd:YAG 532nm (long pulse) - continued

Pulmonary Surgery:
Palliative treatment of benign and malignant pulmonary airway obstructions, including Squamous Cell Carcinoma, Adenocarcinoma; Carcinoid; Benign Tumors; Granulomas; Benign Strictures.

Thoracic Surgery:
Cutting (incision and excision), coagulating, and vaporizing of soft tissue Thoracic applications including, but not limited to: Isolation of vessels for endartacetomy and/or by-pass grafts, Wedge Resections, Thoractoniy, Formation of Pacemaker pockets. Vaporization, coagulation, incision and excision, debulking, and ablation oflung tissue (Thoracoscopy).

Urology:
All applications including: Superficial urinary bladder tumors, invasive bladder carcinoma; Urethral Strictures; Lesions of the external genitalia (including condyloma acuminata).

IPL 590-1200nm; 626-1200nm; 650-1200nm
Indicated for permanent hair removal.
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

IPL 550-1200nm;570-1200nm
Indicated for photocoagulation of dermatological vascular lesion (i.e. face telangiectasia), photothermolysis of blood vessels (treatment of facial and leg veins), and treatment of benign pigmented lesions.

IPL 400-1200nm
Indicated for inflammatory acne (acne vulgaris).

Prescription Use __X___ (Part 21 C.F.R. 801 Subpart D) AND/OR Over-The-Counter Use____ (21 C.F.R. 807 Subpart C)

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Division of Surgical Devices

510(k) Number K130256

Indications for Use Statement

510(k) Number (if known): K130256

Device Name: MDK Multi-Applications Platform

Indications for Use: continued

Integrated Skin Cooler

The intended use of the integrated cooling system in the MDK Multi-Applications Platform hand-piece is to provide cooling of the skin prior to laser treatment, for the reduction of pain during laser treatment, to allow for the use of higher fluencies for laser treatments such as hair removal and vascular lesion, and to reduce the potential side effects of laser treatments.

Any other different use is considered incorrect.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

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510(k) Number **K130256**